UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,832	12/05/2003	William W. Alston	0136.00	8541

21968 7590 11/13/2006

NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,832	ALSTON ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) *6 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-16,18-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-37 are pending in the current application. Claims 6 and 17 stand withdrawn.

Response to Arguments

Applicant's arguments with respect to claims 1-16,18-35 have been considered, however not persuasive. Applicant argues that claim 1 is to an aerosolization system comprising, inter alia, an aerosolization device comprising a chamber adapted to receive a receptacle containing a pharmaceutical formulation, the receptacle comprising a wall having a weakened portion that opens when a force is applied and according to Applicant Ohiki et al utilizes a conventional capsule and creates an opening there into by advancing perforation pins (21, 23) into the capsule as seen in figures 7 and 8. Therefore, Applicant asserts Ohki et al does not alone render claim 1 unpatentable (see remark filed on 8/22/06). Applicant's attention is invited to Applicant's interpretation of Ohiki's teachings, where Applicant clearly understands and considers that the opening into the capsule is advanced by perforation pins. Therefore, Applicant is to further consider that the perforation into the capsule would not have resulted if the walls of capsule were not inherently weak to begin with. Thus, Ohiki et al teach limitations of claim 1, thereby render claim 1 unpatentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,5,7,9,11,27-29,31,33,36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohki et al. US Patent 5,647,349.

As to claim 1, Ohki et al. disclose an aerosolization system comprising an aerosolization device comprising a chamber (fig.7, 6) adapted to receive a receptacle (fig.7, K); and a receptacle containing a pharmaceutical formulation (col.1 lines 51-56). Ohiki et al further disclose opening into the receptacle by advancing perforation pins, 21 and 23 into the receptacle as seen in figures 7 and 8. Thereby Ohiki et al teach the receptacle comprising a wall having a weakened portion that opens when force is applied. Whereby an opening (in areas Hs, see figs. 7 and 8) into the receptacle may be created at the weakened portion before, during, or after insertion of the receptacle into the chamber by applying a force to the receptacle (see col.1 lines 50-67, and col.2 lines 1-37).

As to claim 2, Ohki et al. disclose a system according to claim 1 wherein the weakened portion comprises a region of the wall altered so as to fracture at a force less than would be necessary without the alteration (see fig.8).

As to claim 3, Ohki et al. Ohiki et al disclose the weakened portion comprises a scored region (see fig.8, areas Hs).

As to claim 4, Ohki et al. disclose wherein the aerosolization device comprises a force applying member to apply a force to the weakened portion to create the opening in the receptacle (fig. 7, 23).

As to claim 5, Ohki et al. disclose wherein the force applying member comprises a moveable portion of the chamber (see fig. 8).

As to claim 7, Ohki et al. disclose wherein the force applying member comprises an opening mechanism (fig.8, 23) slidably moveable within the camber.

As to claim 9, Ohki et al. disclose wherein the receptacle is a capsule (see fig.7, K).

As to claim 11, Ohki et al. disclose wherein the receptacle contains a powder pharmaceutical formulation (see figs.7 and 8).

As to claim 27, Ohki et al. disclose claimed invention as applied to claim 1.

As to claim 28, Ohki et al. disclose claimed invention as applied to claim 2.

As to claim 29, Ohki et al. disclose claimed invention as applied to claim 3.

As to claim 31, Ohki et al. disclose claimed invention as applied to claim 9.

As to claim 33, Ohki et al. disclose claimed invention as applied to claim 11.

As to claim 36, Ohki et al. disclose wherein the moveable portion is considered flexible wall (see figs.7 and 8).

As to claim 37, Ohki et al. disclose claimed invention as applied to claim 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8,10,12-16,18-29,30,32,34, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohki et al. US Patent 5,647,349.

As to claim 8, Ohki et al. do not disclose a system according to claim 7 wherein the opening mechanism comprises an opening member having a blunt tip. **A close review of the applicant's disclosure reveals that the applicant has not established criticalities regarding a particular tip used with the opening member. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to provide an opening member having either a blunt tip or an inclined cut needle tip as disclosed by Ohki where both tips are capable of perforating a capsule.**

As to claim 10, Ohki et al. do not disclose a system according to claim 9 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxyproplycellulose, and agar. **As to claim 10, Chiprich et al. teach capsule wall composition of gelatin and cellulose/starch contents (see col.2 lines 55-68 and col.3 lines 1-18) providing a vehicle for dispensing pre-measured medicaments (see col.3 lines 29-30). Also teach the biodegradable nature of the gelatin capsule provides for consumer acceptance of disposable products. Since the capsules as taught by Chiprich contain a non-hygroscopic plasticizer, they require less moisture resistance in their packaging than traditional soft gelatin capsules and therefore provide cost efficiency because of less expensive packaging materials being required (see col.3 lines 38-45). Therefore, it would have been obvious to one of ordinary skills in the**

art at the time the invention was made to add gelatin and cellulose contents to the wall of Ohki in view of Chiprich for the purposes of creating a medicine dispensing vehicle that requires less moisture resistance in their packaging than traditional soft gelatin capsules, therefore further providing cost efficiency because of less expensive packing materials.

As to claim 12, Ohki et al. do not disclose a system according to claim 11 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 gm. **A close review of the applicant's discloser reveals "a particle size selected to permit penetration into the alveoli of the lungs" (see specification page 18, lines 14-15). The mass median diameter will vary depending on the releasing site/the type of tissue absorbing that medication. Mass median diameter can be made smaller or larger to respectively increase or decrease the absorbent nature of the tissue. The medicine administering device disclosed by Ohki is a powder-state medicine filled in a capsule can be employed for a patient with asthma (see col.1 lines 11-13). Therefore, it would have been obvious to one of ordinary skills in the art while preparing the pharmaceutical formulation particles for an asthma patient with a mass median diameter smaller for the purposes of increasing the absorbent efficiency of the lung tissue to rapidly reduce possible breathing difficulties experienced by an asthma patient.**

As to claim 13, Ohki et al. do not disclose a system according to claim 11 wherein the powder pharmaceutical formulation has moisture content below 5% by

weight. **A close review of the disclosure reveals that the applicant prefers a moisture content below about 10% by weight, usually below about 5% by weight, and preferably below about 3% by weight, also discloses such powder are described in the prior art (see specification page 18, lines 21-25). A range of moisture content (below 10%-below about 3%) presented by the applicant is recognized, however the applicant has not established criticalities between a moisture content of 10% or 3% by weight. As to claim 13, Chiprich et al. teach, a brittle gelatin capsule comprises about 5-15% water by weight. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Ohki in view of Chiprich in order to provide a moisture content of 5-15% since it is well known in the art that a low water content is advantageously used in the process of making a powder-like medicine for the purposes of increasing the drying process of the powder.**

Ohiki et al. teach limitation cited in claims 14-16, and 18-26. As to claim 14, Ohki et al. disclose claimed invention as applied to claim 1. **As to claim 15, Ohki et al.** disclose claimed invention as applied to claim 8. **As to claim 16, Ohki et al. disclose** wherein the force is applied after the receptacle is inserted into the chamber (see fig.7). **As to claim 18, Ohki et al.** disclose claimed invention as applied to claim 3. **As to claim 19, Ohki et al.** disclose claimed invention as applied to claim 3. **As to claim 20, Ohki et al.** disclose claimed invention as applied to claim 4. **As to claims 21-23, Ohki et al.** disclose air or gas stream is formed by user's inhalation. **As to claim 24, Ohki et al.**

disclose claimed invention as applied to claim 9. **As to claim 25, Ohki et al.** disclose claimed invention as applied to claim 11. **As to claim 26, Ohki et al.** disclose claimed invention as applied to claim 12. Ohiki et al disclose structural limitations of claims 14-26 to carry out the method steps cited in claims 14-26. Therefore, method steps as cited in claims 14-16 would have been obvious results of using the device of Ohki et al.

As to claim 30, Ohki et al. disclose claimed invention as applied to claim 8.

As to claim 32, Ohki et al. disclose claimed invention as applied to claim 10.

As to claim 34, Ohki et al. disclose claimed invention as applied to claim 12.

As to claim 35, Ohki et al. disclose claimed invention as applied to claim 13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/11/2006

Shumaya B. Ali
Examiner
Art Unit 3771

TEENA MITCHELL
PRIMARY EXAMINER